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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Paul D. Mannheimer, et al.

Serial No.: 10/798,596

Filed: March 10, 2004

For: PULSE OXIMETER SENSOR WITH
PIECE-WISE FUNCTION

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Group Art Unit: 3768

Examiner: Winakur, Eric Frank

Atty. Docket: TYHC:0075-2/FLE/POW
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APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

This Appeal Brief is being filed in furtherance to the Notice of Appeal mailed on June 1, 2007, and received by the Patent Office on June 4, 2007.

The Commissioner is authorized to charge the requisite filing fee of \$500.00, and any additional fees that may be required, to the credit card listed on the attached PTO-2038. However, if the PTO-2038 is missing, if the amount listed thereon is insufficient, or if the amount is unable to be charged to the credit card for any other reason, the Commissioner is authorized to charge Deposit Account No. 06-1315; Order No. TYHC:0075-2/FLE (P0236S-2).

1. **REAL PARTY IN INTEREST**

The real party in interest is Nellcor Puritan Bennett Incorporated, the Assignee of the above-referenced application by virtue of the Assignment to Nellcor Puritan Bennett Incorporated recorded at reel 012182, frame 0344 and dated September 19, 2001. Accordingly, Nellcor Puritan Bennett LLC, as successor of the Assignee of the above-referenced application, will be directly affected by the Board's decision in the pending appeal.

2. **RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any other appeals or interferences related to this Appeal. The undersigned is Appellants' legal representative in this Appeal.

3. **STATUS OF CLAIMS**

Claims 1-7 and 9-53 are currently pending, claims 1-7, 9-26 and 46-53 are currently under final rejection and, thus, are the subject of this Appeal.

4. **STATUS OF AMENDMENTS**

As the instant claims have not been amended at any time, there are no outstanding amendments to be considered by the Board.

5. **SUMMARY OF CLAIMED SUBJECT MATTER**

The application includes five independent claims, namely, claims 1, 6, 11, 13 and 46, all of which are the subject of this Appeal. The subject matter of these claims is summarized below.

With regard to the aspect of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments include an oximeter sensor (e.g., sensor 15) comprising a light emitter (e.g., LEDs 14) for directing light at a patient (e.g., patient tissue 18) and a light detector (e.g., photosensor

16) mounted to receive light from the patient. *See, e.g.*, Application, page 4, line 32 – page 5, line 10; page 5, lines 23-24; FIG. 1. Further, present embodiments include a memory (e.g., memory 12) storing a first formula for determining oxygen saturation, a second formula for determining oxygen saturation, a first set of coefficients corresponding to a wavelength of the light emitter for use in the first formula, and a second set of coefficients corresponding to the wavelength of the light emitter for use in the second-formula, wherein the first formula differs from the second formula. *See, e.g.*, Application, page 5, line 23 – page 6, line 2; page 6, lines 8-25; page 6, line 28 – page 9, line 23; FIG. 1.

With regard to the aspect of the invention set forth in independent claim 6, discussions of the recited features of claim 6 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments include an oximeter sensor system (e.g., FIG. 1) comprising a light emitter (e.g., LEDs 14) for directing light at a patient (e.g., patient tissue 18) and a light detector (e.g., photosensor 16) mounted to receive light from the patient. *See, e.g.*, Application, page 4, line 32 – page 5, line 10; page 5, lines 23-24; FIG. 1. Further, present embodiments include a memory (e.g., memory 12), mounted in a sensor (e.g., sensor 15) or between the sensor and an oximeter monitor (e.g., pulse oximeter 17), the memory storing an indication of a breakpoint, first and second sets of coefficients corresponding to a same wavelength of the light emitter, and first and second formulas for determining oxygen saturation, the oximeter monitor selecting between the first and second sets of coefficients and the first and second formulas for determining oxygen saturation based at least in part on the breakpoint. *See, e.g.*, Application, page 4, line 32 – page 5, line 7; page 5, line 23 – page 6, line 2; page 6, lines 8-25; page 6, line 28 – page 9, line 23; FIG. 1.

With regard to the aspect of the invention set forth in independent claim 11, discussions of the recited features of claim 11 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments

include an oximeter sensor (e.g., sensor 15) comprising a light emitter (e.g., LEDs 14) for directing light at a patient (e.g., patient tissue 18) and a light detector (e.g., photosensor 16) mounted to receive light from the patient. *See, e.g.*, Application, page 4, line 32 – page 5, line 10; page 5, lines 23-24; FIG. 1. Further, present embodiments include a memory (e.g., memory 12) storing at least two different algorithms, and a plurality of alternate values of oxygen saturation or ratio-of-ratio values used in the at least two different algorithms to determine oxygen saturation, the plurality of values corresponding to the same mean wavelength of the same light emitter. *See, e.g.*, Application, page 5, line 23 – page 6, line 2; page 6, lines 8-25; page 6, line 28 – page 9, line 23; FIG. 1.

With regard to the aspect of the invention set forth in independent claim 13, discussions of the recited features of claim 13 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments include a pulse oximeter system (e.g., FIG. 1) comprising a pulse oximeter sensor (e.g., sensor 15), which comprises a light emitter (e.g., LEDs 14) for directing light at a patient (e.g., patient tissue 18) and a light detector (e.g., photosensor 16) mounted to receive light from the patient. *See, e.g.*, Application, page 4, line 32 – page 5, line 10; page 5, lines 23-24; FIG. 1. Further, the pulse oximeter sensor may comprise a memory (e.g., memory 12) storing a first formula for determining oxygen saturation, a second formula for determining oxygen saturation, a first set of coefficients corresponding to a wavelength of the light emitter for use in the first formula, and a second set of coefficients corresponding to the wavelength of the light emitter for use in the second formula, wherein the first formula differs from the second formula. *See, e.g.*, Application, page 5, line 23 – page 6, line 2; page 6, lines 8-25; page 6, line 28 – page 9, line 23; FIG. 1. Additionally, present embodiments may include a pulse oximeter monitor (e.g., pulse oximeter 17) configured to receive communications from the pulse oximeter sensor and configured to perform calculations using one or both of the first and second formulas to estimate oxygen saturation in blood of the patient. *See, e.g.*, Application, page 4, line 32 – page 5, line 10; page 5, lines 23-24; FIG. 1.

With regard to the aspect of the invention set forth in independent claim 46, discussions of the recited features of claim 46 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments include oximeter system comprising an oximeter sensor and an oximeter monitor. The oximeter sensor may comprise a light emitter configured to direct light at a patient and a light detector mounted to receive light from the patient. *See, e.g.*, Application, page 4, line 32 – page 5, line 10; page 5, lines 23-24; FIG. 1. Further the oximeter sensor may comprise a sensor memory storing a first formula for determining oxygen saturation, a second formula for determining oxygen saturation, a first set of coefficients corresponding to a wavelength of the light emitter, and a second set of coefficients corresponding to the wavelength of the light emitter. *See, e.g.*, Application, page 5, line 23 – page 6, line 2; page 6, lines 8-25; page 6, line 28 – page 9, line 23; FIG. 1. The oximeter monitor may comprise a calculation mechanism configured to determine a blood oxygen saturation in the patient, wherein the calculation mechanism selects and utilizes the first set of coefficients in the first formula for a first range of oxygen saturation values and selects and utilizes the second set of coefficients in the second formula for a second range of oxygen saturation values, wherein the first range differs from the second range. *Id.*

6. **GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

Appellants respectfully urge the Board to review and reverse the Examiner's only ground of rejection in which the Examiner rejected claims 1-7, 9-26, and 46-53 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

7. **ARGUMENT**

As discussed in detail below, the Examiner has improperly rejected the pending claims. Further, the Examiner has misapplied long-standing and binding legal precedents and principles in rejecting the claims under 35 U.S.C. § 112, first paragraph. Accordingly, Appellants respectfully request full and favorable consideration by the

Board, as Appellants strongly believe that claims 1-7, 9-26, and 46-53 are currently in condition for allowance.

A. **Ground of Rejection:**

The Examiner rejected claims 1-7, and 9-26, and 46-53 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner maintained a previous rejection of claims 1-7 and 9-17 under 35 U.S.C. § 112, first paragraph. Additionally, it appears that the Examiner applied the previous rejection of claims 1-7 and 9-17 under 35 U.S.C. § 112, first paragraph, to claims 18-26 and 46-54, which were added after the initial rejection of claims 1-7 and 9-17, without specifically addressing the added claims. In the previous rejection, the Examiner stated the following:

Claims 1 - 7 and 9 - 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed discloses that the memory stores coefficients (used in formulas) and breakpoints (used to indicate when to use a particular formula) [see originally filed Figures 2 and 3 and the descriptions thereof]. Further, the originally filed specification teaches that different formulas may be used for different sections of the saturation curve. However, these formulas are resident in the sensor reader/monitor. There is no teaching or suggestion that the sensor memory include the formulas or algorithms, only that the coefficients and breakpoints are stored therein. As such, the claims contain subject matter that was not adequately described by the specification as originally filed, and therefore Applicant did not have possession of the claimed invention at the time the application was filed.

Office Action mailed June 26, 2006, page 2.

The Appellants respectfully traverse this rejection. Regarding the written description requirement, the initial burden of proof regarding the sufficiency of the written description falls on the Examiner. Accordingly, the Examiner must present evidence or reasons why persons skilled in the art would not recognize a description of the claimed subject matter in the applicant's disclosure. *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q. 90, 96 (C.C.P.A. 1976). The Board is also reminded that the written description requirement does not require the claims to recite the same terminology used in the disclosure. *Ellipse Corp. v. Ford Motor Co.*, 171 U.S.P.Q. 513, 517 (7th Cir. 1971), *aff'd*, 613 F.2d 775 (7th Cir. 1979), *cert. denied*, 446 U.S. 939 (1980). Moreover, any information contained in any part of the application as filed, including the specification, claims, and drawings, may be added to other portions of the application without introducing new matter. M.P.E.P. § 2163.06.

The Appellants respectfully submit that one of ordinary skill in the art with the benefit of the present disclosure would recognize the invention set forth in the claims based on the written description found in the present disclosure. Specifically, one of ordinary skill in the art would recognize that the specification clearly teaches that the formulas may be stored in the sensor memory. However, it should be noted that the specification need not specifically state that "formulas" may be stored on the sensor memory, since the claims are not required to recite the same terminology used in the disclosure. *See Ellipse Corp. v. Ford Motor Co.*, 171 U.S.P.Q. 513, 517 (7th Cir. 1971), *aff'd*, 613 F.2d 775 (7th Cir. 1979), *cert. denied*, 446 U.S. 939 (1980).

As the Examiner has recognized, the formulas may be stored on the monitor. Office Action mailed June 26, 2006, page 2. However, the formulas also may be stored on the sensor memory, as recited by independent claims 1, 6, 11, 13, and 46. For example, the specification discloses compressing "functions" to allow storage of those functions on a limited sensor memory. *See Application*, page 9, lines 15-17. The specification states that "any function can be used for the formulas for determining oxygen saturation For a limited *sensor memory*, the *function* representation may be

compressed.” Application, page 9, lines 15-17 (emphasis added). The term “function” is defined as “a mathematical correspondence that assigns exactly one element of one set to each element of the same or another set.” WEBSTER’S NINTH NEW COLLEGIATE DICTIONARY 498 (1989). The term “formula” is defined as “a general fact, rule, or principle expressed in usually mathematical symbols.” WEBSTER’S 485 (1989). Hence, both terms have similar meanings. This similarity, combined with the context in which the specification uses these terms, would clearly lead any reasonable person to the conclusion that the specification discloses that the function or formula may be stored on the sensor memory. Indeed, one of ordinary skill in the art would recognize that if the formulas were only stored on the monitor memory, there would be no need to compress them for a limited *sensor* memory.

In the “Response to Arguments” section of the Final Office Action, the Examiner stated that the Appellant’s arguments have been unpersuasive because the portion of the specification quoted by the Appellants does not explicitly or inherently teach storing the functions on the sensor memory. To support this argument, the Examiner stated the following:

As the quoted passage indicates that “any function can be used” and “[a]ny representation of a function could be used,” the chosen function could be quite complex, involving multiple variables and constants, thereby requiring multiple coefficients to be stored on the memory. Such a situation would overwhelm the capacity of the limited sensor memory. However, mathematical assumptions and approximations may be employed to “compress” the function to remove the need to store some of the coefficients and allow the limited memory to store the needed data.

Final Office Action mailed December 15, 2006, page 3.

First, in the portion of the specification relied on by the Examiner, the Board should note that the term “function” is again being used interchangeably with the term “formula.” But still further, Appellants stress that, in the portion of the specification

quoted above, a direct correlation is made between the compression of the *function* and limited sensor memory. Again, the specification states, “For a limited *sensor memory*, the *function* representation may be compressed.” Application, page 9, lines 15-17 (emphasis added). There is no mention of how compressing the *function* may reduce the number of coefficients that are stored. Accordingly, Appellants assert that, in context, a reasonable interpretation of the text quoted from the specification above would suggest that the *functions* are stored on the limited sensor memory and may be compressed to facilitate their storage.

The Examiner made an additional argument in the “Response to Arguments” section of the Final Office Action that the Appellants would like to address. Specifically, the Examiner stated the following:

[T]he specification still does not teach or suggest storing two sets of coefficients and two functions, as set forth in the claims. In fact, if the formulas were stored on the memory this would eliminate the need to store coefficients on the memory, as this would merely duplicate information contained in the formula without enhancing the usefulness of the device.

Final Office Action mailed December 15, 2006, page 4.

Appellants assert that the present application clearly discloses the use of two functions or formulas for determining oxygen saturation. *See e.g.*, Application, page 3, lines 30-33. Indeed, many of the originally filed claims recite a memory storing first and second different formulas for determining oxygen saturation. Further, in view of the disclosure relating to storage of functions on a limited sensor memory, one of ordinary skill in the art would recognize that two functions would be stored on a sensor memory in certain embodiments. Additionally, as set forth throughout the specification, multiple different coefficients may be utilized with a *single* formula depending on the application. *See, e.g.*, Application, page 6, lines 3-25. For example, to accomplish the “piece-wise” function to which the present application is primarily directed, a single formula may have

one set of coefficients for a first saturation range *and* a second set of coefficients for a second saturation range. Accordingly, storing coefficients in addition to formulas on a single memory would not be a mere duplication of stored information, as suggested by the Examiner.

The Examiner also made a supplemental argument in the Advisory Action mailed on May 2, 2007 that the Appellants would like to address. Specifically, the Examiner stated the following:

Although there is a correlation between the terms “limited sensor memory”, “function” and “compressed” in the quoted portion, there is no further explanation of how the compressing is achieved. Applicant contends that somehow the functions are compressed to allow their storage on the memory, and that this interpretation is not contrary to the teachings of the specification. Examiner is not persuaded that such an interpretation is reasonable, given, as previously noted, that the remainder of the specification is concerned with storing coefficients on the sensor memory, but storing functions on the monitor.

Advisory Action mailed May 2, 2007, page 2.

Regarding this statement, Appellants first assert that the correlation between the terms “limited sensor memory,” “function,” and “compressed” would be understood by one of ordinary skill in the art, as discussed in detail above. Second, Appellants assert that the one of ordinary skill in the art would understand how to compress the function representation (data defining the function representation) for more efficient storage on a limited memory, since many techniques for data compression exist. Further, Appellants reiterate that Appellants do not believe that there is any support for limiting the scope of the present application to storing formulas/functions *only* on a monitor, as suggested by the Examiner.

In view of the teaching of the present application, the Appellants respectfully assert that the specification clearly teaches storing formulas in the sensor memory in such

a way as to reasonably convey possession of the claimed invention to one of ordinary skill in the art at the time of filing. Furthermore, Appellants respectfully assert that the Examiner has not met his burden of setting forth evidence or any supportable reasoning why one of ordinary skill in the art would *not* recognize the claimed invention in the disclosure *despite the teachings in the application noted above*. See *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976).

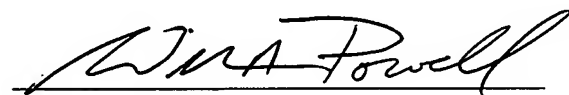
In view of the remarks set forth above, the Appellants respectfully submit that a person of ordinary skill in the art would recognize a description of the subject matter of claims 1, 6, 11, 13, and 46 in the disclosure. For at least these reasons among others, the Appellants respectfully request that the Board overturn the rejections under 35 U.S.C. § 112, first paragraph. Further, Appellants request that the Board overturn the rejection of claims depending from claims 1, 6, 11, 13, and 46 based on their dependency from these independent claims.

Conclusion

Appellants respectfully submit that all pending claims are in condition for allowance. However, if the Examiner or Board wishes to resolve any other issues by way of a telephone conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Date: August 1, 2007


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8. **APPENDIX OF CLAIMS ON APPEAL**

Listing of Claims:

1. An oximeter sensor comprising:
a light emitter for directing light at a patient;
a light detector mounted to receive light from the patient; and
a memory storing a first formula for determining oxygen saturation, a second formula for determining oxygen saturation, a first set of coefficients corresponding to a wavelength of the light emitter for use in the first formula, and a second set of coefficients corresponding to the wavelength of the light emitter for use in the second-formula, wherein the first formula differs from the second formula.
2. The oximeter sensor of claim 1 wherein the coefficients are dependent on a mean wavelength of the light emitter.
3. The oximeter sensor of claim 1 wherein the memory further stores a value indicating a signal breakpoint between the first and second formulas.
4. The oximeter sensor of claim 1 wherein at least one of the different formulas is a nonlinear formula.
5. The oximeter sensor of claim 1 wherein the different formulas are linear formulas.
6. An oximeter sensor system comprising:
a light emitter for directing light at a patient;

a light detector mounted to receive light from the patient; and
a memory, mounted in a sensor or between the sensor and an oximeter monitor, the memory storing an indication of a breakpoint, first and second sets of coefficients corresponding to a same wavelength of the light emitter, and first and second formulas for determining oxygen saturation, the oximeter monitor selecting between the first and second sets of coefficients and the first and second formulas for determining oxygen saturation based at least in part on the breakpoint.

7. The system of claim 6 wherein the coefficients are dependent on a mean wavelength of the light emitter.

9. The system of claim 6 wherein at least one of the formulas is a nonlinear formula.

10. The system of claim 6 wherein the formulas are linear formulas.

11. An oximeter sensor comprising:
a light emitter for directing light at a patient;
a light detector mounted to receive light from the patient; and
a memory storing at least two different algorithms, and a plurality of alternate values of oxygen saturation or ratio-of-ratio values used in the at least two different algorithms to determine oxygen saturation, the plurality of values corresponding to the same mean wavelength of the same light emitter.

12. The sensor of claim 11 wherein the values correspond to different coefficients or formulas used for different ranges of oxygen saturation.

13. A pulse oximeter system comprising:
a pulse oximeter sensor comprising:
a light emitter for directing light at a patient;
a light detector mounted to receive light from the patient; and
a memory storing a first formula for determining oxygen saturation, a second formula for determining oxygen saturation, a first set of coefficients corresponding to a wavelength of the light emitter for use in the first formula, and a second set of coefficients corresponding to the wavelength of the light emitter for use in the second formula, wherein the first formula differs from the second formula; and
a pulse oximeter monitor configured to receive communications from the pulse oximeter sensor and configured to perform calculations using one or both of the first and second formulas to estimate oxygen saturation in blood of the patient.
14. The system of claim 13 wherein the coefficients are dependent on a mean wavelength of the light emitter.
15. The system of claim 13 wherein the memory further stores a value indicating a signal breakpoint between the first and second formulas.
16. The system of claim 13 wherein at least one of the different formulas is a nonlinear formula.
17. The system of claim 13 wherein the different formulas are linear formulas.

18. The oximeter sensor of claim 1 wherein at least one of the formulas comprises a spline function.
19. The oximeter sensor of claim 1 wherein at least one of the formulas comprises a ratio-of-ratios function.
20. The oximeter sensor of claim 3 wherein the value comprises an indication of oxygen saturation.
21. The system of claim 6 wherein at least one of the formulas comprises a spline function.
22. The system of claim 6 wherein at least one of the formulas comprises a ratio-of-ratios function.
23. The system of claim 6 wherein the breakpoint comprises an oxygen saturation value.
24. The system of claim 13 wherein at least one of the formulas comprises a spline function.
25. The system of claim 13 wherein at least one of the formulas comprises a ratio-of-ratios function.
26. The system of claim 15 wherein the value comprises an oxygen saturation level.
46. An oximeter system comprising:
an oximeter sensor, comprising:

a light emitter configured to direct light at a patient;
a light detector mounted to receive light from the patient; and
a sensor memory storing a first formula for determining oxygen saturation, a second formula for determining oxygen saturation, a first set of coefficients corresponding to a wavelength of the light emitter, and a second set of coefficients corresponding to the wavelength of the light emitter;

an oximeter monitor, comprising:

a calculation mechanism configured to determine a blood oxygen saturation in the patient, wherein the calculation mechanism selects and utilizes the first set of coefficients in the first formula for a first range of oxygen saturation values and selects and utilizes the second set of coefficients in the second formula for a second range of oxygen saturation values, wherein the first range differs from the second range.

47. The system of claim 46 wherein the coefficients are dependent on a mean wavelength of the light emitter.

48. The system of claim 46 wherein at least one of the different formulas is a nonlinear formula.

49. The system of claim 46 wherein the different formulas are linear formulas.

50. The system of claim 46 wherein at least one of the different formulas comprises a spline function.

51. The system of claim 46 wherein at least one of the different formulas comprises a ratio-of-ratios function.

52. The system of claim 46 wherein the sensor memory further stores a value indicating a signal breakpoint between the first and second formulas.

53. The system of claim 52 wherein the value comprises an oxygen saturation level.

9. **EVIDENCE APPENDIX**

None.

10. **RELATED PROCEEDINGS APPENDIX**

None.